DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-015/S-005

Unimed Pharmaceuticals, Inc.
Attention: Judy Athey
Manager, Regulatory Affairs
Four Parkway North
Suite 200
Deerfield, IL 60015-2544

Dear Ms. Athey:

Please refer to your supplemental new drug application dated February 22, 2001, received February 23, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AndroGel® (testosterone gel).

We acknowledge receipt of your submission dated February 26, 2001.

This "Changes Being Effected" supplemental new drug application provides for revisions to the patient and package inserts to update safety information and to update the labeling component number. The following revisions were made:

Patient Insert:

1. Changed the component number from A.09.063.0031530 Issued 7/00 to A. 09.063.0032727 85-0004-00 Issued 12/00.

2. **Who should not take AndroGel®?** Section

   "AndroGel® **must not be used by women** or by those individuals with known hypersensitivity to any of its components, including individuals who are hypersensitive to testosterone that is chemically synthesized from soy."

Package Insert:

1. Changed the component number from A.09.063.0031529 Issued 9/00 to A. 09.063.0032728 85-0005-00 Issued 12/00.

2. **CONTRAINDICATIONS** section

   …."AndroGel® should not be used in patients with known hypersensitivity to any of its ingredients, including testosterone USP that is chemically synthesized from soy."

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted February 22, 2001, patient package insert submitted February 22, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jeanine Best, M.S.N., R.N., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Susan Allen, M.D., M.P.H.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research